Submitter : Mrs. Esther Scherb
Organization : Latham & Watkins, LLP
Category : Attorney/Law Firm
Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mrs. Terese Ghio **Date:** 09/16/2005

Organization : Ligand Pharmaceuticals Incorporated

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Ligand Pharmaceuticals Incorporated welcomes the opportunity to comment the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on July 25, 2005. Ligand is a San Diego based emerging specialty pharmaceutical company that discovers, develops and markets innovative small molecule drugs and one biological to address critical, unmet medical needs with four Orphan-designated products for oncology and dermatology: ONTAK (denileukin diftitox), TARGRETIN capsules (bexarotene), TARGRETIN gel and PANRETIN gel (alitretinoin), and AVINZA in the area of chronic pain management (morphine sulfate extended-release capsules) One of Ligand's products, ONTAK, is a recombinant DNA-derived cytotoxic fusion protein that is a covered by Medicare under Part B in both the hospital outpatient setting and in the physician office. ONTAK received orphan designation from the FDA and is used to treat the limited population of patients with advanced stages of Cutaneous T-Cell Lymphoma (CTCL). Approximately 850 patients were treated with ONTAK in the past year and we estimate less than 35% were covered by Medicare under Part B. This product and the patient population it services truly meet the intent of the legislature?s definition of Orphan Product. CTCL is a rare cancer and while the prognosis for early stage patients is quite good with median survival of 12 years, later stage patients for whom ONTAK is an approved therapy and principally utilized have a median survival of 2.5-5 years. (Siegel R. JCO, Vol 18, No. 15, 2000 pp 2908-2925). Patients most often succumb to opportunistic infection and so selecting therapies that are less immuno/myelosuppressive is an important consideration. ONTAK is one of the very few therapies FDA approved for late stage CTCL. In addition, because it is less immuno/myelosuppressive than available chemotherapies it is often the patient's only hope of a response to this aggressive disease. Ligand respectfully submits the following comments to CMS for purposes of ensuring adequate reimbursement and access to ONTAK (J9160) for the limited Medicare population in need of this important therapy.

Ligand supports in full the comments submitted by the Biotechnology Industry Organization (BIO) and the National Organization for Rare Disorders (NORD). Ligand sincerely appreciates the opportunity to comment on these rules and the open and interactive approach CMS has taken with stakeholders across the medical and health care communities. Please contact us for questions or to request additional information related to our products or ideas and positions on Medicare policy. Please see attached formal comments.

CMS-1501-P-585-Attach-1.PDF

#585

September 16, 2005

BY ELECTRONIC DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Administrator McClellan:

Ligand Pharmaceuticals Incorporated welcomes the opportunity to comment the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on July 25, 2005 (the "Proposed Rule"). Ligand is a San Diego based emerging specialty pharmaceutical company that discovers, develops and markets innovative small molecule drugs and one biological to address critical, unmet medical needs with four Orphan-designated products for oncology and dermatology: ONTAK (denileukin diftitox), TARGRETIN capsules (bexarotene), TARGRETIN gel and PANRETIN gel (alitretinoin), and AVINZA in the area of chronic pain management (morphine sulfate extended-release capsules)

One of Ligand's products, ONTAK, is a recombinant DNA-derived cytotoxic fusion protein that is a covered by Medicare under Part B in both the hospital outpatient setting and in the physician office. ONTAK received orphan designation from the FDA and is used to treat the limited population of patients with advanced stages of Cutaneous T-Cell Lymphoma (CTCL). Approximately 850 patients were treated with ONTAK in the past year and we estimate less than 35% were covered by Medicare under Part B. This product and the patient population it services truly meet the intent of the legislature's definition of Orphan Product. CTCL is a rare cancer and while the prognosis for early stage patients is quite good with median survival of 12 years, later stage patients for whom ONTAK is an approved therapy and principally utilized have a median survival of 2.5-5 years. (Siegel R. JCO, Vol 18, No. 15, 2000 pp 2908-2925). Patients most often succumb to opportunistic infection and so selecting therapies that are less immuno/myelosuppressive is an important consideration. ONTAK is one of the very few therapies FDA approved for late stage CTCL. In addition, because it is less

immuno/myelosuppressive than available chemotherapies it is often the patient's only hope of a response to this aggressive disease. Ligand respectfully submits the following comments to CMS for purposes of ensuring adequate reimbursement and access to ONTAK for the limited Medicare population in need of this important therapy.

Ligand's Comments on the CMS Proposed Rule for 2006 rates

Access for Medicare patients.

Lack of equitable Medicare reimbursement in the hospital outpatient setting and physician setting has historically had a negative impact on patient access to this product, which is, for many patients the only option for this debilitating, and sometimes deadly, disease. Our research indicates that the historical reimbursement structure unfairly discriminated against many patients, including those patients in rural areas. The proposed methodology of ASP+6% is inadequate for Ontak not because Ligand discounts the product resulting in a lower ASP but because CMS has not responded to our questions for clarification on inclusion of service fees in the calculation.

This methodology has resulted in access issues for patients in the physician office setting. Feedback has indicated actual acquisition costs in the past year that, in some cases, exceeded reimbursement by as much as $100 per vial in the physician office setting. (see Table 1) This has resulted in an un-due influence on the site of medical practice by shifting patients between the physician offices to the hospital outpatient sites based on the current reimbursement rate structure. Now CMS wants to impose this same methodology to the hospital outpatient setting and we are very concerned that this will leave patients with no access. This is especially true because CMS has in their interim final rule for the CAP program excluded Ontak.

Table 1:

2005 data	ASP+6% Rate	WAC	Delta
1st Q	$ 1,205.53	$ 1,308.00	($102.47)
2nd Q	$ 1,212.83	$ 1,308.00	($95.17)
3rd Q	$ 1,243.93	$ 1,360.00	($116.07)
4th Q	$ 1,252.93	$ 1,360.00	($107.07)

In addition to concerns expressed directly to us by physicians currently under the ASP+6% rate that the rate is woefully insufficient, the GAO data supports that the median purchase price for hospitals was almost exactly the same as the WAC price for 2003.

Special Consideration Needed for Payment Rate For Ontak.

Ligand applauded CMS for last year's rulemaking to "continue making separate payments for orphan drugs based on their currently assigned APCs." CMS correctly recognized that paying for these therapies as SCODs would result in "lower payments which could impede beneficiary access to these unique drugs dedicated to the treatment of rare diseases." CMS appropriately chose to exercise its authority to set payment rates for designated orphan drugs and as a result CMS set in the OPPS rule to cover ONTAK at "88% AWP or 106 percent of the ASP, whichever is higher".

We respectfully ask that CMS consider a temporary reimbursement rate for one year that is closer to the actual hospital acquisition cost such as WAC or some other special methodology to ensure appropriate reimbursement for this orphan product. It is critically important to our

patients that they have access to this therapy and we would like to work with CMS to monitor access during 2006 to develop a long term solution to this issue.

In addition to the fact that the ASP+6% methodology is woefully inadequate for Ontak, outpatient departments generally have significantly higher staffing costs such as nursing salaries and deal with a more vulnerable patient base than what is common practice in the physician office. We also believe that the 2% pharmacy handling and service costs in inadequate for Ontak and would like to discuss a higher rate for a special class of products, like Ontak, that require special handling.

Ontak is a very special product requiring very special handling at both the wholesaler and the physician's office. ONTAK has some very unique requirements including:

a. Its treatment regimen: 3-5 vials/day for 5 days on a 21 day cycle. Therefore patients must usually begin treatment on a Monday. This requires very coordinated planning with the patient and the wholesaler to order the product for drop shipment on a Friday.
b. ONTAK is stored at our distributor at -80 degrees C and must remain frozen and shipped in special packaging to the physician who in turn must keep it frozen at -10 degrees C until just before use.
c. ONTAK has specific requirements in its label for solution preparation.
d. Patients typically require pre-medication with steroids (oral or IV) and extra intravenous hydration prior to treatment with ONTAK.
e. In addition, label warnings which require additional monitoring include Acute Hypersensitivity-type reaction (69% patients) and Vascular Leak Syndrome (27% patients). The latter of which can be delayed (usually in first two weeks) and require follow-up phone calls by staff to monitor.

We urge CMS monitor patient access and increase rates as necessary to ensure that Medicare beneficiaries retain access to critical therapies. We also ask CMS to implement the APC Panel's recommendation to monitor for "precipitous" drops in reimbursement rates during the transition to an ASP-based payment.

Ligand supports in full the comments submitted by the Biotechnology Industry Organization (BIO) and the National Organization for Rare Disorders (NORD). Ligand sincerely appreciates the opportunity to comment on these rules and the open and interactive approach CMS has taken with stakeholders across the medical and health care communities. Please contact us for questions or to request additional information related to our products or ideas and positions on Medicare policy.

Respectfully submitted by,

Terese M. Ghio
Vice President Government Affairs and EH&S
Ligand Pharmaceuticals
tghio@ligand.com
858-550-7569

Submitter : **Mr. John Manter** **Date: 09/16/2005**

Organization : **Mr. John Manter**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Status Indicators

I am requesting that this classification be developed and reorganized in a logical and coherent set that would provide some sort of unifying framework for OPPS.

Especially status indicator H, which for years was limited to pass through transitional payment for devices, seemed expanded arbitrarily to include prostate brachytherapy seeds. I suggest a unique status inidicator for radioactive implants and nucleides paid by cost to charge. Also request clarification on what specific cost to charge ratio will be used to caluculate I-125 implants and clarification of what is meant by "per source".

SI "E" needs to be broken down/expanded, so that the items that are excluded from Medicare by statue and items not excluded by statute but not covered for other reasons , have different status indicators. In other words, I am suggesting using the SIs for purposes in addition to claims processing. Those codes with status E that may be paid by another code might be moved to status A or status B.

Status A might be expanded to indicate exactly what fee schedule the HCPCS is paid under, or at least provide a comprehensive list in Addendum D.

I also ask that for inpatient only indicator C, that you clarify Addendum D, where you state " Not paid under OPPS. Admit patient. Bill as inpatient." Can hospitals literally automatically do this ?

I also suggest reforming status indicator B so that if Medicare outpatient HCPCS are paid to physicians, they also are paid to hospitals. For example, payment for high osmolar contrast (gastrografin) should be based similar to that for low osmolar contrast.

Thanks for your consideration.

Submitter : Mr. Joseph Corcoran **Date:** 09/16/2005

Organization : New York Eye and Ear Infirmary

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Cochlear implantation is an FDA approved and well established technology that restores hearing to adults and children with severe to profound hearing loss, who do not derive benefit from hearing aids. Cochlear implants are ?life transforming,? taking recipients from silence and isolation to a productive and interactive life. Cost utility analysis (1) confirms cochlear implantation as a fiscally effective medical intervention.

I write to express our deep concern about proposed changes to the Hospital Outpatient Prospective Payment System, which will reduce the already inadequate reimbursement for this procedure. If Medicare reimbursement does not cover the cost of cochlear implantation, there will be a powerful disincentive to provide this service. Cochlear implant programs will be forced to close by hospitals unwilling to lose money. Medicare recipients will be denied a wonderful therapeutic alternative to a life of disabling silence.

The New York Eye and Ear Infirmary is fully aware that the hospital outpatient payment system methodology is flawed and, therefore, we know that it is difficult for CMS to accurately track actual device costs. Nevertheless, if implemented, the proposed $21,739 ($25,905 with our area wage adjustment) level of reimbursement, a 14% reduction, will have a severe impact on Medicare beneficiary access to cochlear implantation.

We do not wish to curtail the recently expanded cochlear implantation program here at the Infirmary. However, the proposed reimbursement would barely cover the cost of the device (the Advanced Bionics 9-15-05 list price is $25,750 and it has risen each of the last three years), let alone cover the absolute minimum of $2,000 of related costs involved with the surgery which include evaluation, medical education ($96 per case) and OR time in the Ambulatory Surgery Unit ($1,936).

While most insurance companies provide benefits that cover the cost, based on your proposed reduction to a pre-wage adjusted reimbursement of $21,739, we stand to lose a minimum of over $2,000 on every case; our `06 budget projects over 20 Medicare cases, based on recent physician recruitment.

Please also note that:
? Cochlear implantation provides extraordinary benefits to our patient population. Specifically, it increases the Medicare beneficiary?s ability to remain self-sufficient and independent.

? The cost effectiveness of cochlear implantation has been well documented by a large body of evidence-based literature and has been accepted by both the medical profession and by insurers (see footnote below).

? Only a limited number of centers (approximately 350 nationwide) provide cochlear implantation. The proposed level of reimbursement will undoubtedly further reduce the number of centers offering implantation and hamper access for implants and follow-up care for Medicare beneficiaries and others.

On behalf of the thousands of hearing impaired senior citizens who will someday need cochlear implantation, I ask that you review the available data and help establish a reasonable and fair reimbursement rate, one that will allow implant centers to function in a fiscally responsible way. In that context, it seems particularly important for CMS to substitute accurate external device cost data and recalculate the relative weight of cochlear implantation. Alternatively, we implore you to set the 2006 OPPS payment at 100% of the 2005 payment rate plus the inflation and other update factors applied to all APCs.

We appreciate CMS? recognition of the impact of payment rates on access to care and its consideration of our comments.

Joseph P. Corcoran
President and CEO

1. Cost utility of the cochlear Implant in Adults. Arch Otolaryngology, 1999; 125:1214-18

Submitter : Mr. Martin Wong **Date:** 09/16/2005

Organization : POINT Biomedical Corporation

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-588-Attach-1.DOC

CMS-1501-P-588-Attach-2.DOC

September 16, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

RE: Proposed Changes to the OPPS Payment System and 2006 Payment Rates

Issue: **New Technology APC**

Dear Dr. McClellan:

POINT Biomedical Corporation is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

We would like to thank CMS for the opportunity to make recommendations regarding the proposal to require the submission of a CPT code application as part of the New Technology APC criteria.

New Technology APCs

CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application be submitted to CMS as a part of the application for a New Technology APC. CMS is also proposing to require a letter from the AMA acknowledging the CPT code application.

POINT Biomedical Corporation is concerned that the AMA CPT Editorial Panel may not be an appropriate forum for a federally mandated new technology decision. This requirement may add unnecessary delay of new technology to Medicare beneficiaries preventing rapid availability of new technology as intended by the MMA legislation.

The AMA CPT Editorial Panel is a private organization that is not subject to procedural protections that are required for public policy. AMA meetings are closed to the public and the basis for decisions are not available to the public, including hospitals and physicians. The AMA CPT Editorial Panel has no voting representatives from the medical technology industry and manufacturer community. Further, the panel is not subject to the protections

POINT

of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act.

Clearly, the requirement of the submission to the AMA CPT Editorial Panel would require involvement of an organization that may not be accountable as are all other agencies that are subject to federal public policy decisions. This requirement may be an unlawful delegation of federal decision making to a private organization.

Category I codes are typically assigned to a procedure that has become an accepted standard of care thus defeating the purpose of adoption of new technology. If manufacturers are forced to apply for a CPT code before sufficient information is available, it is likely that the CPT Editorial Panel would assign a Category III (emerging technology) code that often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries, and many commercial payers.

If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives of manufacturers on the decision making panel, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients. Until this time we recommend that CMS eliminate the proposed requirement that manufacturers submit a CPT application prior to submission of a New Technology APC application to CMS.

New technology continues to offer important treatment for Medicare patients. Appropriate and timely payment for new technologies permit Medicare beneficiary's full access to high quality care in the hospital outpatient setting just as other patients covered by private insurance.

We hope that CMS will take these issues under consideration during the development of the HOPPS Final Rule and eliminate the proposed requirement for a CPT application submission prior to the New Technology APC application.

Should CMS staff have additional questions, please contact me.

Sincerely,

Marty Wong
Senior Director
(650) 412-1775
mwong@pointbio.com

Submitter : Mr. John Manter **Date:** 09/16/2005

Organization : Mr. John Manter

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Evaluation and Management

Please provide a signal of the expected direction for this area.
I suggest a one year trial of paying hospital five different rates for the five levels, for hospital and physician payment system equality.

Submitter : Dr. David Gollaher

Date: 09/16/2005

Organization : California Healthcare Institute

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-590-Attach-1.PDF

#590

C H I CALIFORNIA HEALTHCARE INSTITUTE
WWW.CHI.ORG

September 16, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates) – Device-Dependent APCs; New Technology APCs; on Pass-Throughs; Orphan Drugs; Vaccines; and Drug Administration

Dear Administrator McClellan:

The California Healthcare Institute (CHI) welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on July 25, 2005 (the "Proposed Rule").[1] CHI represents the full biomedical sector of the California economy and unites more than 250 of California's leading biomedical firms, universities, and private research institutes in support of biomedical science, biotechnology, and pharmaceutical and medical device innovation. California is the global leader in biomedical R&D, with more than one-third of all U.S. biotechnology and medical device firms, turning

[1] 70 Fed. Reg. 42673 (July 25, 2005).

HEADQUARTERS
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La Jolla, California 92037
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SACRAMENTO
980 Ninth Street, Suite 2200
Sacramento, California 95814

scientific discoveries into medical products at an unprecedented rate. California companies lead the nation in bringing to market frontline therapies for diseases such as AIDS, breast cancer, stroke, and diabetes.

As the advocate for California's biomedical industry, CHI has commented in the past that deficient OPPS rates could deprive Medicare beneficiaries' access to much needed therapies – not only to therapies that exist today but those on the horizon that offer patients and their families a much brighter future. It is essential that Medicare adequately reimburse hospital outpatient departments for their costs of providing innovative drugs, biologicals, radiopharmaceuticals, and devices. Medicare beneficiaries rely on hospital outpatient departments, including those of our member hospitals, to provide advanced treatments for cancer and other complex conditions. For many patients, hospital outpatient departments are the only settings where they can receive appropriate care. Patients whose conditions are particularly complicated often must be treated in outpatient departments because their needs cannot be met in a physician office. Similarly, some treatment regimens, such as those involving radiopharmaceuticals, advanced devices, and some clinical trials, cannot be administered in physician offices. Due to the added complexity of the therapies provided in outpatient departments, the more intense needs of many of their patients, and the increased regulatory oversight applicable to hospitals, we believe the cost of care in outpatient departments is at least as great as in physician offices. To protect beneficiary access to care in the appropriate hospital outpatient setting, Medicare reimbursement for services performed in hospital outpatient departments must be at least equal to payment for the same services provided in physician offices.

We have appreciated CMS' efforts to address our concerns as it implements the payment reforms required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and refines the OPPS. In the Proposed Rule, CMS announces several payment reforms that we believe will protect beneficiary access to critical therapies. For example, the proposals to reimburse most separately paid drugs[2] at 106 percent of average sales price (ASP), to make an add-on payment for pharmacy handling costs, and to begin using the new Current Procedural Terminology (CPT®) codes for drug administration services will help ensure that hospitals are adequately reimbursed for the costs of providing advanced drug therapies. We support CMS' proposal to reimburse radiopharmaceuticals in 2006 based on the hospital's charges converted to costs. We also support the proposals to pay separately for all 5HT3 anti-emetic therapies and low osmolar contrast material and not to apply an "equitable adjustment" to any drugs. In addition, we commend the proposed interpretation of the pass-through status

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[2] Throughout our comments, we use "drugs" to refer to both drugs and biologicals.

criteria that would allow devices inserted or implanted through an orifice or a surgical incision to qualify for this status.

Although we generally support many of CMS' proposals, CHI is concerned about the details of some aspects of the Proposed Rule. With respect to devices, CMS should protect access to advanced technologies by limiting payment to no less than the 2005 rates, plus inflation and other applicable adjustments. CMS also should apply the same limitation to payment reductions for device-related procedures that are reassigned from New Technology APCs to clinical APCs. CMS should not implement its proposal to require applicants for assignment to New Technology APCs first to submit applications for CPT® codes because this additional step will impede access to advanced treatments by frustrating efforts to achieve appropriate reimbursement. We also recommend that CMS delay implementation of the proposed reduction in payment for multiple diagnostic imaging procedures and continue to study whether such a reduction is justified.

Regarding drugs, CHI concurs with recommendations of the Advisory Panel on Ambulatory Payment Classification Groups (the APC Panel) regarding payment for drugs, pharmacy handling costs, and drug administration services. As recommended by the APC Panel, CMS should monitor all drugs during the transition to reimbursement at ASP plus 6 percent to prevent "precipitous" drops in reimbursement rates that could harm access to these therapies. CMS also should follow the APC Panel's recommendation to make an add-on payment for pharmacy handling and service costs, reconsider whether the proposed amount is adequate, and make an additional payment for the overhead and handling costs associated with packaged drugs. In addition, CMS should delay implementation of the pharmacy overhead charges codes until January 2007 and continue to study means of collecting cost data. We also support the APC Panel's recommendation to reimburse FluMist®, the intranasal influenza vaccine, using the reasonable cost methodology applied to all other influenza vaccines and to reimburse its administration on par with administration of other influenza vaccines, as suggested by the APC Panel. We advise CMS to monitor patient access closely and increase rates as needed to protect beneficiary access to care. We are particularly concerned that ASP plus 6 percent may not be adequate for intravenous immune globulin (IVIG) and drugs and used to treat rare disorders.

Although CHI supports CMS' temporary rate-setting methodology for radiopharmaceuticals, we recommend that CMS use the hospital's general cost to charge ratio in this calculation, not a department-specific ratio. We urge CMS to develop a future rate-setting methodology for radiopharmaceuticals through close consultation with stakeholders. CMS also must ensure that hospitals are reimbursed adequately for drug administration services by paying for additional hours of infusions and allowing hospitals to bill for multiple "initial" codes. The

agency should provide clear and timely guidance to hospitals on the use of the new drug administration codes, particularly for administration of substances such as monoclonal antibody agents and other biological response modifiers that should be billed as chemotherapy administration, and adjust administration payment rates as needed to protect access to care.

We discuss these recommendations in more detail below.

I. Device Dependent APCs

CHI thanks CMS for recognizing that significant payment reductions may threaten hospitals' ability to provide advanced medical devices. CMS proposes to limit the reductions applicable to device-dependent APCs whose proposed 2006 median cost is at least 15 percent less than the adjusted 2005 median cost.[3] We agree that payment reductions must be moderated, and we are concerned that CMS' proposal does not do enough to ensure that payment rates will remain adequate to protect beneficiary access to devices. For many devices, the 2005 OPPS rates do not provide adequate reimbursement for the full cost of the device and the associated resources and procedures. Adjusting median cost to equal only 85 percent of the 2005 level will not improve the adequacy of these rates. For all device-dependent APCs for which 2006 median costs are less than the 2005 adjusted median costs, CHI recommends that CMS adjust the median costs to the 2005 levels. These adjusted medians also should be increased by inflation and other update factors that apply to all APCs.

In the Proposed Rule, CMS notes that it used external data to set device-dependent APC rates in prior years, but it appears that the agency has not used external data this year. The 2006 rates will be based on claims data from 2004, when hospitals voluntarily coded devices used in procedures. Many of these claims may not include the correct device code or any device code at all. Given the small number of claims that passed CMS' device edits, we are concerned that the agency's data may not be sufficient to set appropriate rates. We understand that several organizations and manufacturers submitted data this year, and we urge CMS to use this information in setting rates for 2006, as it has done in recent years.

In addition, CHI requests that CMS reconsider the effects of charge compression on its rate-setting methodology. The OPPS methodology for setting rates for device-dependent APCs applies a single cost-to-charge ratio to hospital charges for devices. This methodology fails to account for the differences in hospital mark-ups for devices; higher-cost devices tend to have smaller mark-ups than lower-cost devices. Using a single cost-to-charge ratio leads to under-

[3] 70 Fed. Reg. at 42714.

reimbursement for higher-cost devices, potentially discouraging hospitals from offering Medicare beneficiaries the most clinically appropriate devices. CHI urges CMS to work with stakeholders, including hospitals and device manufacturers, to develop solutions to the charge compression problem.

II. New Technology APCs

CHI is concerned that CMS' proposed changes to requirements for assigning services to New Technology APCs will delay access to innovative therapies. CMS proposes to require applicants for New Technology APCs to first submit an application for a new CPT® code. CMS claims that this requirement "will encourage timely review by the wider medical community as CMS is reviewing the service for possible new coding and assignment to a New Technology APC under the OPPS."[4] We believe that, in practice, the requirement will impose a significant obstacle to beneficiary access to new technology.

The process of applying for a new CPT® code is lengthy and involves months of gathering information on the technology and its use, working with the relevant specialty societies to garner support for the code and to develop the clinical vignette, consultation with the CPT® Editorial Panel staff, and review by the relevant CPT® committees. In order to obtain a Category I code, the new technology must have widespread usage across the country and in multiple locations, and its efficacy must be documented in U.S. peer review journal articles. If these requirements are not met, and specialty society support is not garnered, the technology likely will be granted a Category III code and almost universally be denied coverage by every payor across the country.

Requiring applicants to undertake these tasks in addition to the New Technology APC request process will discourage manufacturers from seeking classification in an appropriate New Technology APC. Rather than helping CMS meet its goal of "ensuring that Medicare beneficiaries have timely access to the most effective new medical treatments and technologies in clinically appropriate settings,"[5] this requirement will be another barrier to care because it will lead to fewer advanced technologies receiving appropriate OPPS payment. We urge CMS to not implement this proposal in the final rule.

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4 Id. at 42707.
5 Id.

III. Other New Technology Services

CMS proposes to reassign 10 device-related procedures currently assigned to New Technology APCs to clinical APCs.[6] Half of these procedures would be paid significantly less in 2006 than in 2005. To protect continued access to these procedures and the advanced devices used to perform them, we urge CMS to reconsider the proposed reassignments. If CMS determines to finalize the reassignments, we recommend that it consider means to dampen the effect of any payment reductions, such as using external data to set payment rates or assigning the procedures to different APCs. We also recommend that CMS apply the same limitation on reductions in payment for these procedures that applies to other device-dependent APCs.

IV. Pass-Through Device Categories

CHI commends CMS for proposing to modify its interpretation of the criteria for establishing new pass-through device categories. CMS proposes to consider a device eligible for pass-through status if it is surgically inserted or implanted through a natural orifice or a surgical incision.[7] This proposal recognizes that advanced devices that can be implanted or inserted through less invasive procedures offer considerable benefits for Medicare beneficiaries. Granting pass-through status to these devices would help to protect beneficiary access to them. We support the proposed change in interpretation of the regulations, and we urge CMS to implement this change. We also ask the agency to revise the regulation text at 42 C.F.R. § 419.66(b)(3) to reflect this interpretation. We recommend that CMS replace the words "surgically implanted or inserted" with "implanted or inserted, through a natural or surgically created orifice or through a surgically created incision."

V. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status – NonPass-Throughs; Orphans

A. Payment for Drugs and Biologicals

In general, CHI supports CMS' proposal to reimburse most separately paid drugs without pass-through status, including the specified covered outpatient drugs, at 106 percent of ASP. Applying this rate to almost all drugs should help simplify the OPPS for CMS and providers. CMS will benefit from using data it already collects and updates, rather than setting rates by applying several reimbursement formulas to multiple sources of pricing data. Providers will

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[6] 70 Fed. Reg. at 42709.
[7] 70 Fed. Reg. at 42721.

appreciate this methodology because it allows reimbursement rates to adjust as market conditions change. By treating almost all separately paid drugs alike, this methodology also reduces incentives for providers to select drugs based on their reimbursement, and instead helps to ensure Medicare beneficiaries' access to the most appropriate therapies for their particular conditions. We urge CMS to implement this logical proposal in the final rule.

We also urge CMS to monitor access to drugs during the transition to payment at ASP plus 6 percent. Access to some therapies, particularly IVIG and drugs used to treat rare diseases, could be threatened if the OPPS rates do not adequately compensate hospitals for acquiring these drugs. We recommend that CMS increase the reimbursement for drugs as needed to protect access to care. Additionally, as recommended by the APC Panel, CMS should monitor the reimbursement rates for all drugs for "precipitous" drops during this transition. CMS has applied a 15 percent threshold for certain drugs in the past,[8] and a 15 percent threshold also is proposed for device-dependent APCs.[9] CHI suggests a 15 percent threshold be applied in this situation as well. Volatility among payment rates could impede hospitals' ability to plan their budgets, and inadequate rates could create access issues for patients.

CHI commends CMS' proposal to apply the ASP-based payment methodology to the two biological products that had been linked by an "equitable adjustment."[10] We agree with the decision to "permit market forces to determine the appropriate payment"[11] for these therapies, rather than setting rates through government interference. We urge CMS to implement this proposal in the final rule.

Finally, CHI agrees with the proposal to pay separately for all 5HT3 anti-emetic therapies regardless of whether they meet the $50 packaging threshold.[12] CMS correctly recognizes anti-emetics are integral parts of many treatment regimens, and the unique qualities of each anti-emetic can produce different effects in each patient. To ensure that Medicare beneficiaries have access to the particular anti-emetic that is most effective for them as determined by the beneficiary and his or her physician, we urge CMS to finalize this proposal. We also support to proposal to pay separately for all low osmolar contrast material,[13] and we ask CMS to include this proposal in the final rule.

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8 67 Fed. Reg. 66718, 66769 (Nov. 1, 2002).
9 70 Fed. Reg. at 42714.
10 70 Fed. Reg. at 42727.
11 Id.
12 Id.
13 Id.

B. Payment for Radiopharmaceuticals

Because CMS does not have ASP data for radiopharmaceuticals, the agency proposes to reimburse these products in 2006 based on the hospital's charge for each radiopharmaceutical agent, converted to costs using the hospital's specific cost-to-charge ratio (CCR).[14] CMS proposes this methodology as a means of representing hospital actual acquisition costs for radiopharmaceuticals.

While CHI generally supports CMS use of the CCR methodology, it is concerned that it may fail to appropriately convert charges to "average acquisition costs," particularly for higher cost therapies that are susceptible to charge compression. Application of department-specific ratios, in particular, could result in inadequate payment, harming patient access to care. In order to protect patient access to medical care while CMS gathers data upon which to base OPPS payment in future years, we recommend that CMS apply hospitals' general CCR and also that it ensure that the OPPS payment for each effected product does not fall below 95 percent of its 2005 HOPPS rate.

CHI is also concerned that CMS intends to require reporting of ASP for radiopharmaceuticals. Congress demonstrated its recognition of the complexities of radiopharmaceuticals by exempting them from the ASP payment methodology. Clearly, Congress intended that radiopharmaceuticals not be subject to ASP reporting requirements and calculations. CHI is concerned that despite this exemption, CMS seeks to require ASP reporting and apply the methodology specifically rejected by Congress for these products to the hospital outpatient setting.

As CMS works to develop a rate-setting methodology for future years, we ask the agency to work closely with hospitals and manufacturers to ensure that the costs of acquiring, handling, and providing these products are reflected appropriately in
OPPS rates.

C. Payment for Pharmacy Handling Costs

CHI supports CMS' proposal to compensate hospitals for their service and handling costs associated with furnishing advanced therapies.[15] As the Medicare Payment Advisory Commission (MedPAC) recently reported, hospitals' pharmacy

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14 Id.
15 Id. at 42730.

handling costs range from 25 to 33 percent of pharmacy-related direct expenses.[16] When Congress enacted the MMA's payment reforms, it recognized that ASP-based reimbursement likely would not compensate hospitals for the costs of safely preparing, storing, and transporting drugs. We agree that an additional payment is needed, but we urge CMS to reconsider whether its proposed payment of 2 percent of ASP for separately paid drugs will be sufficient reimbursement for these important services. We urge CMS to follow the APC Panel's recommendation to reassess its proposal in light of hospital and industry data regarding these costs and develop rates that more accurately reflect pharmacy service and handling costs. We also support the APC Panel's recommendation that CMS make add-on payments for the handling costs of packaged drugs, as well as for separately paid therapies.

In addition, CHI generally supports CMS' proposal to begin collecting data on pharmacy service costs in 2006 for use in setting future payment rates. Under this proposal, hospitals would report their charges by using new C-codes for pharmacy handling services.[17] If hospitals use a consistent approach to setting their charges and report the appropriate C-code for each service, this proposal could lead to more appropriate payment rates in the future. Unfortunately, as MedPAC explained in its report, few hospitals currently charge for their handling costs, and among those hospitals no systematic, consensus based approach exists for measuring these costs.[18] We are concerned that neither hospitals nor CMS will be able to develop such an approach before the new codes become effective. We recommend that CMS delay implementation of the codes until January 1, 2007, as recommended by the APC Panel, and continue to refine the codes and develop instructions for their use.

VI. Vaccines

CHI commends CMS for continuing to reimburse virtually all influenza and pneumococcal vaccines at reasonable cost.[19] This payment methodology will protect hospitals' ability to provide these critical vaccines to Medicare beneficiaries by ensuring that they will be adequately reimbursed regardless of any price fluctuations. We are concerned, however, that the agency has not proposed applying the same methodology to FluMist®, the intranasal influenza vaccine. Unlike all of the other influenza vaccines, CMS proposes to classify FluMist® (90660) as status E, meaning that Medicare does not cover the code, does not recognize it, or does not provide separate payment for it. Instead, CMS proposes

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16 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

17 70 Fed. Reg. at 42730.

18 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 143.

19 70 Fed. Reg. at 42733.

only to pay $5.00 for the administration of FluMist®.[20] Because this extremely low rate will not cover the cost of the vaccine and the administration service, hospitals could be discouraged from offering FluMist®, decreasing vaccination options during next year's flu season. Because there is no reason to distinguish this influenza vaccine from all others, CHI agrees with the APC Panel's recommendation to reimburse FluMist® (90660) on a reasonable cost basis and to reimburse its administration on par with administration of other influenza vaccines by clarifying that hospitals should use procedure code G0008 to bill for the administration of FluMist®. We urge CMS to implement this recommendation and to exempt FluMist® and its administration from coinsurance and deductible, similar to all other influenza vaccines.

VII. Drug Administration

CHI supports CMS' proposal to use the new CPT® codes for drug administration services, effective January 1, 2006. By using these new, more specific codes, CMS should be able to collect more detailed charge data on drug administration services, leading to more appropriate payment rates in the future. Until these data are collected, we are concerned that the two-year old data used to set rates lack the specificity necessary to set appropriate rates for all the codes. We are concerned that these rates, on top of the new ASP-based rates and the extremely low proposed add-on for pharmacy overhead costs, will not provide adequate reimbursement for hospitals' costs of providing critical drug treatments. We note that CMS responded to similar concerns in the physician office setting by revaluing payment for the administration codes and by creating a demonstration project to pay oncologists to collect data on their patients' pain, fatigue, and nausea. CMS has not proposed any similar adjustments under the OPPS, however. CHI urges CMS to monitor access to drug and biological therapies in the hospital outpatient setting and adjust rates as needed to protect access to care.

Additionally, we urge CMS to reimburse hospital outpatient departments for all the drug administration services they provide. If finalized, CMS' proposal to pay only for "initial" codes, when combined with the CPT® coding guideline to bill only one "initial" code per encounter, would reimburse hospitals for only a portion of the services they provide. For example, if a hospital administers a one hour hydration infusion and a two hour chemotherapy infusion to a Medicare beneficiary, it would bill CPT® codes 90780 (IV infusion, hydration, up to 1 hour), 96410 (IV infusion technique; up to 1 hour, single or initial substance/drug), and 96412 (each additional hour, 1 to 8 hours). Under the current OPPS rule, the hospital would be paid for 90780 and 96410; payment for 96412 would be packaged. In the physician

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[20] The administration codes for FluMist® are 90473 and 90474. These codes are packaged into APC 1491 that has a payment rate of $5.00.

office setting, all three codes would be reimbursed. Under the Proposed Rule and the new coding guidelines, the hospital would bill the new codes that correspond to these services, but would be paid for 96410 only. Under the new coding guidelines, the hydration administration would be billed as an "additional" infusion and the Proposed Rule payment would package payment for this service. Payment for the additional hour of chemotherapy administration would continue to be packaged as well. The proposed OPPS payment rules, when combined with the new coding guidelines, would produce a drastic cut in reimbursement for these drug administration services.

CHI firmly believes that CMS did not intend for hospitals' reimbursement for drug administration services to be cut so severely when it proposed to implement the new, more detailed drug codes. We recommend that CMS correct this problem by instructing hospitals to ignore the coding instructions to bill only one "initial" code per encounter. CMS should continue to allow hospitals to bill multiple "initial" codes. CMS also should pay separately for additional hours of infusions, using 2004 and 2005 claims data to set rates for these services in 2006. These revisions will help ensure that hospitals are appropriately reimbursed for providing critical drug administration services.

As CMS introduces the new codes to hospital outpatient departments, we recommend that the agency provide clear instructions on their use. CMS provided guidance to physicians before implementing the codes this year. We believe that similar guidance, in the form of transmittals, Medlearn Matters articles, and an explanation in the final rule, is needed to help hospitals use the codes appropriately. Specifically, the guidance should include a clear explanation to bill the administration of substances such as monoclonal antibody agents and other biological response modifiers as chemotherapy administration.[21] The crosswalk table in the final rule and the titles of the chemotherapy administration APCs should be updated to reflect these changes.

VIII. Multiple Diagnostic Imaging Procedures

CMS proposes to reduce payment by 50 percent for second and subsequent imaging procedures within the same family when performed in the same session.[22]

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[21] CMS Transmittal 129, Change Request 3631 (Dec. 10, 2004) states, "Under the new codes, chemotherapy administration codes apply to parenteral administration of non-radionuclide anti-neoplastic drugs and also to anti-neoplastic agents provided for the treatment of noncancer diagnoses (e.g., cyclophosphamide for autoimmune conditions), or to substances such as monoclonal antibody agents and other biologic response modifiers." This same guidance should be included in the preamble of the final rule and be transmitted to hospitals and contractors.

[22] 70 Fed. Reg. at 42751.

CHI urges CMS to reconsider this proposal, as recommended by the APC Panel. Although we understand that some imaging procedures require fewer resources when a second service is provided in the same session, we disagree with CMS' conclusion to apply a 50 percent reduction to the second and subsequent services. Many of the resources required to perform each imaging procedure, such as technologist time, contrast material, and machine depreciation and maintenance, are the same for each image, and the per-image costs are not reduced when multiple services are provided during the same session. The proposed drastic cut in reimbursement could harm beneficiary access to these services and could dissuade hospitals from continuing to invest in advanced imaging technology. We ask the agency to study this issue further to determine what an appropriate adjustment, if any, would be for additional imaging procedures.

IX. Conclusion

CHI appreciates this opportunity to comment on the Proposed Rule, and we look forward to working with CMS to protect Medicare beneficiaries' access to life-improving drug therapies. We hope our suggestions will help CMS address these important issues in the final rule. In brief, we urge CMS to:

- Protect access to advanced medical devices by limiting payment to no less than 2005 rates, plus inflation and other applicable adjustments;
- Not require applicants for assignment to New Technology APCs first to submit applications for CPT® codes;
- Reconsider the proposed reassignments of device-related procedures from New Technology APCs to clinical APCs and implement any adjustments needed to dampen payment reductions for these procedures;
- Finalize the proposed interpretation of the criteria for pass-through status to allow devices inserted or implanted through an orifice or a surgical incision to qualify for this status and revise the regulation text accordingly;
- Implement its proposal to reimburse most separately paid drugs at 106 percent of ASP, while monitoring patient access closely and increasing rates as needed to protect beneficiary access to care, especially for drugs used to treat rare conditions and IVIG;
- Monitor all drugs during the transition to ASP plus 6 percent to prevent precipitous drops in reimbursement rates;
- Reimburse FluMist® using the reasonable cost methodology and reimburse its administration on par with other influenza vaccines;
- Reconsider whether the proposed add-on payment for pharmacy handling and overhead costs is adequate and make an additional payment for the handling costs associated with packaged drugs;

- Delay implementation of the C-codes for pharmacy handling charges and continue to study alternate means of collecting this data;
- Provide reimbursement for additional hours of infusions, allow hospitals to bill for multiple "initial" codes, and provide clear and timely guidance on the use of the new drug administration codes; and
- Not implement the proposed reduction in payment for multiple imaging procedures and continue to study whether any reduction is justified.

Please contact Todd Gillenwater, Vice President, Public Policy, at (858) 551-6677 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

David Gollaher

David L. Gollaher, Ph.D.
President and CEO

Submitter : Mr. Kenneth Raske
Organization : GNYHA
Category : Hospital
Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1501-P-591-Attach-1.PDF

#591

Greater New York Hospital Association
555 West 57th Street / New York, N.Y. 10019 / (212) 246 - 7100 / (212) 262 - 6350
Kenneth E. Raske, President

September
Sixteen
2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Subject: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, *Federal Register,* Vol. 70, No. 141, July 25, 2005, pp. 42673-43011. [CMS-1501-P]

Dear Dr. McClellan:

On behalf of the over 175 not-for-profit and public hospitals in the metropolitan New York area that comprise the membership of the Greater New York Hospital Association (GNYHA), I greatly appreciate this opportunity to comment upon the Centers for Medicare & Medicaid Services' (CMS's) proposed rule for the hospital outpatient prospective payment system (OPPS) and calendar year 2006 payment rates.

OPPS has provided a major challenge for the hospital industry since its implementation in 2000 because of the complexity of the payment system and because the multitude of coding and billing protocols has required hospitals to make difficult changes to their billing systems. In addition, problems with the data have caused instability in the ambulatory payment classification (APC) rates from year to year, which makes it very difficult for hospitals to predict revenue and develop budgets for Medicare outpatient services.

Nonetheless, we appreciate the hard work that CMS staff put into the proposed rule, and we are committed to working with CMS and our member hospitals to continue to make improvements in the OPPS.

The following are our comments and recommendations this year.

PHARMACY OVERHEAD AND DRUG HANDLING PAYMENT RATE ADJUSTMENT

Currently, CMS reimburses hospitals for most separately-payable drugs based on the median cost of the drug as derived from hospital claims data. Since hospital charges for drugs include pharmacy overhead and drug handling costs, these costs are included in the APC rates. For 2006, CMS is proposing to change the APC payment rate for these drugs to the average sales price (ASP) plus 6%, the same rate paid by Medicare in the physician office setting. The calculation of the ASP for drugs does not incorporate pharmacy overhead and drug handling costs.

Earlier this year, the Medicare Payment Advisory Commission (MedPAC) released a study, based on a small sample of hospital data, which found that pharmacy overhead costs are significant and that they vary greatly by drug category, as shown in the following table.[1] Therefore, since the ASP does not incorporate pharmacy overhead and drug handling costs, a payment add-on is required.

Category	Description	Relative Weight
1	Orals	0.36
2	Injection/Sterile Preparation	1.00
3	Single IV Solution/Sterile Preparation	1.28
4	Compounded/Reconstituted IV Preparations	1.61
5	Specialty IV or Agents	2.70
6	Cytotoxic Agents	5.33
7+	Radiopharmaceuticals	

CMS does not have a complete set of hospital charge data on pharmacy overhead and drug handling costs, so the Agency proposed an across-the-board add-on of 2%. Thus, the payment rate for separately-payable drugs would be ASP plus 8%. CMS states that this payment rate is, on average, the mean cost of drugs as derived from hospital claims data, which, again, include pharmacy overhead and drug handling costs.

Given the wide variability that MedPAC found in the overhead and handling component of the different drug categories, we think that an across-the-board add-on in inappropriate. We are very concerned about the losses that would accrue to hospitals with a more expensive mix of drug categories, especially hospitals serving a high proportion of cancer patients. Therefore, in the absence of more complete data, we recommend that CMS vary the add-on applied to different drug categories.

Furthermore, we think it is important that CMS implement a variable add-on in 2006 because we do not believe that the Agency will have the data necessary to estimate better weights in the near future. That is because we do not believe that the approach CMS recommended to obtain the data is sound. CMS has proposed to collect data on pharmacy overhead and drug handing costs by establishing a series of C-codes that hospitals would use to report separate charges for pharmacy overhead and drug handling costs associated with separately-payable drugs.

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[1] Medicare Payment Advisory Commission, *Report to the Congress: Issues in a Modernized Medicare Program*, June 2005, p.137-155.

GNYHA strongly opposes this proposal because it is currently infeasible for hospitals to implement and because developing systems to make it feasible would be unduly burdensome. Instead, we believe that CMS should work with the industry to develop a more reasonable approach to collecting these data.

Recommendations:

- For 2006, CMS should vary the add-on representing pharmacy overhead and drug handling costs by drug category rather than applying a 2% across-the-board add-on.

- CMS should not implement the proposed C-codes to collect data on pharmacy overhead and drug handling costs, but instead should work with the industry to investigate alternative ways to collect the data.

REDUCED PAYMENT FOR MULTIPLE IMAGING PROCEDURES

CMS has proposed to implement a multiple procedure discount for imaging services under which hospitals would be paid the full APC payment rate for the highest paid imaging service and 50% of the APC rate for all other imaging procedures rendered within the same "family" of procedures during the same session. Under this proposal, imaging procedures would be grouped into 11 families of services based on contiguous body areas.

This proposal is based on a similar one that CMS made in the Medicare Physician Fee Schedule proposed rule for 2006. However, while the physician proposal was based on an analysis of physician data, the hospital proposal was not. Indeed, CMS admitted in the proposed rule that it does not have data on hospital costs that are incurred in furnishing multiple imaging procedures during the same session.

While it might be reasonable to assume that there are some economies associated with providing multiple imaging procedures during a single session in a hospital-based setting, it is completely inappropriate for CMS to propose an arbitrary discount. Therefore, we strongly oppose this proposal.

Recommendation:

- CMS should not implement a payment reduction for multiple imaging services provided in the same session until it has hospital data to prove that such a discount is warranted and to support a specific discount.

Outlier Payment Policy

CMS has proposed to cut the OPPS outlier payment pool in half (i.e., from 2% of total OPPS payments to 1%), and to increase the fixed-dollar threshold by 34% (i.e., from $1,175 to $1,575) in order to spend the lower amount. GNYHA strongly opposes this proposal because we believe that a properly-functioning outlier pool of at least 2% is needed. The APC rates are still so

volatile that we are not at all assured that the unit cost estimates upon which they are based are accurate. Therefore, losses could easily represent systematic risk and a 2% outlier pool is necessary to mitigate the impact on hospitals and—more importantly—their patients.

We are concerned, however, about the extent to which the OPPS outlier program is functioning properly. That is, we do not know whether CMS is under-, correctly- or over-spending the OPPS funding set aside for outliers. Therefore, we strongly urge CMS to publish a comparison of the amount of funds set aside for outliers with the amount of funds paid out as outliers since the inception of the OPPS.

Recommendations:

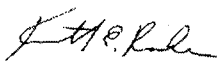
- CMS should maintain the outlier pool at 2% of total OPPS spending and not increase the fixed-dollar threshold. In addition, CMS should describe the services that qualify for outlier payments.

- CMS should disclose the historical percentage of total OPPS payments that has been paid as outliers, just as it does for the inpatient PPS.

We appreciate your consideration of these comments. If you have any questions or would like further information, please contact Elisabeth R. Wynn, Director of Finance, at (212) 259-0719 or wynn@gnyha.org.

My best.

Sincerely,



Kenneth E. Raske
President

Submitter : Mr. James Adams **Date:** 09/16/2005

Organization : Coast Plaza Doctors Hospital

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

Hello,
Thank you for the opportunity for comment (see attachment).
James Adams

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Kenneth McKusick **Date:** 09/16/2005

Organization : Nuclear Medicine APC Task Force

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

This is a supplement to comments submitted 9.15.05 by the Nuclear Medicine APC Task Force. MedPAC just sent a letter affirming that they did NOT intend to imply that Handling Costs were included in hospital charges. This letter is attached.

Kenneth McKusxick MD Chair NMAPC TF

CMS-1501-P-593-Attach-1.PDF

CMS-1501-P-593-Attach-2.PDF

#593

September 16, 2005

Dr. Kenneth A. McKusick
Chair
Nuclear Medicine APC Task Force

Dear Dr. McKusick:

Thank you for your letter regarding pharmacy handling costs in hospital outpatient departments for radiopharmaceuticals.

MedPAC's June 2005 Report to Congress highlighted the costs hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals. As you may know, we reported that hospitals that make their own nuclear materials have higher handling costs than most nuclear medicine departments. We also found in our study and site visit that "hospital outpatient departments that furnish radiopharmaceuticals...must purchase special shielding equipment and dose calibrators, monitor employee exposure to radiation, employ radiation safety officers, and comply with specific regulations regarding radioactive materials, waste, storage, and disposal, licensure, quality assurance and safety," as you stated in your letter. Our report was not meant to infer that these actions would not happen in facilities that purchase unit doses of radiopharmaceuticals. Rather, our report was highlighting the fact that hospitals preparing their own radiopharmaceuticals in house are likely to have higher costs.

We will continue to follow this issue and appreciate your feedback on our study.

Sincerely,

Mark E. Miller

Submitter :

Date: 09/16/2005

Organization : **AARP**

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-594-Attach-1.DOC

September 15, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, Maryland 21244-8018

RE: **CMS-1501-P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates**
70 Federal Register 42674, July 25, 2005

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed rule changing Medicare payment policies under the hospital outpatient prospective payment system (OPPS) for calendar year 2006 payment rates. We take this opportunity to provide comments on the proposed policy for multiple diagnostic imaging procedures and the proposed beneficiary copayments for calendar year (CY) 2006. We also identify additional legislative changes that Congress could take to further improve the OPPS for Medicare beneficiaries.

Multiple Diagnostic Imaging Procedures

Currently, under the OPPS, hospitals billing for diagnostic imaging procedures receive full APC payments for each service on a claim, regardless of how many procedures are performed, and whether or not contiguous areas of the body are studied in the same session.

Section XIV of the preamble proposes new CMS policy that would make a 50-percent reduction in the OPPS payments for some second and subsequent imaging procedures performed in the same session, for individual services described by codes within one group not across groups.

AARP supports the proposed policy on the basis that it would reduce the level of coinsurance for Medicare beneficiaries. We also agree that the policy could result in a higher level of efficiencies when imaging is performed on contiguous body areas because the patient and equipment have already been prepared for the second and subsequent procedures, potentially yielding resource savings in hospital costs for areas such as technical preparation, supplies and clerical time.

Beneficiary Copayment

Under the OPPS, CMS pays for hospital outpatient services on a rate-per-service basis that varies according to the ambulatory payment classification (APC) group to which the service is assigned. Despite the fact that outpatient services are covered by Part B, beneficiary coinsurance is significantly higher than the standard 20 percent for other Part B services. This is due to a "glitch" in the law that based a beneficiary's coinsurance on 20 percent of charges rather than Medicare's approved amount.

We are pleased that in 1997, and in subsequent years, Congress took steps to enact statutory changes to correct this problem by gradually reducing beneficiary coinsurance to 20 percent of Medicare's payment.

In Section II of the preamble, CMS specifies the proposed beneficiary copayment for all services paid under the OPPS in CY 2006, and in calendar years thereafter. The specified percentage is 40 percent of the Ambulatory Payment Classification (APC) payment rate. The reduction of the maximum coinsurance to 40 percent in 2006 is the last scheduled reduction amount specified in law. Unfortunately, Medicare beneficiaries still pay higher coinsurance rather than the appropriate 20 percent for other Part B services. According to CMS estimates, average beneficiary coinsurance for all outpatient services are expected to fall to 30 percent – which is still significantly higher than the standard 20 percent paid for other Part B services.

AARP advocates for statutory changes that would accelerate the phase-down of the coinsurance and provide beneficiaries with some relief from out-of-pocket costs for Medicare Part B services. Without any additional statutory changes, restoring the beneficiary coinsurance for all outpatient services will be accomplished gradually over the next 20 or more years. Furthermore, while the statute limits beneficiary liability for copayments for a service to the inpatient hospital deductible for the applicable year -- there is still no limit to the amount of coinsurance that a beneficiary can incur or pay per year or even for a single outpatient encounter.

We urge CMS to work with Congress to restore the beneficiary coinsurance for hospital outpatient services to the appropriate level. Thank you for the opportunity to comment. If you have any questions about our comments please contact Andrea Price of our Federal Affairs Department at 434-3770.

Sincerely,

David Certner
Director
Federal Affairs

Submitter : **Ms. Elizabeth Funk** **Date: 09/16/2005**

Organization : **Mental Health & Substance Abuse Corps. of MA**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

MHSACM, Inc.

251 West Central Street, Suite 21, Natick, Massachusetts 01760 (508) 647-8385 / Fax (508) 647-8311

Elizabeth Funk, President/CEO Ellen Attaliades, MA, Chairman

September 15, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-1501-P: Proposed Changes to Hospital Outpatient PPS 2006 Rates

Dear Dr. McClellan:

On behalf of the members of Mental Health and Substance Abuse Corporations of Massachusetts, Inc. (MHSACM), I want to thank you for the opportunity to submit comments on the proposed CMS rate reduction for Partial Hospitalization services. MHSACM is a statewide association representing more than 100 community-based mental health and substance abuse providers that deliver treatment services to individuals and families throughout the state, and serve approximately 117,000 Massachusetts residents on any given day. We are very concerned that this proposed rate cut will severely restrict our members? ability to maintain viable programs that deliver intensive treatment to a very high risk population of clients in lieu of inpatient hospitalization.

The clients referred to Partial Hospitalization services are in acute distress and extremely vulnerable. The majority of clients have histories of suicidality, assualtive behavior, co-occurring mental health and substance use disorders, trauma and abuse, commitments to hospitalization as well as homelessness and other medical complications, and often live in the community under a guardianship. Our community?based Partial Hospitalization programs provide these high risk clients with an intensive level of clinical treatment as well as the structure and support needed to remain successfully in a community setting.

A 15 percent rate reduction is unacceptable in light of the ever increasing cost of operating these programs. The overhead costs have increased in every area including all utility costs, staff salaries and benefits, insurance, program supplies, transportation, communications and administrative support. Hiring and retaining qualified staff that are willing to dedicate their careers to working with this population of clients is extremely difficult, especially in the high-cost, competitive health care job market of Massachusetts. Our staff are consistently underpaid for working with a population of clients that most health care professionals consider too challenging, too risky and difficult to serve.

We are also very concerned about the methodology used to justify this rate reduction. Cost reports are never reconciled in a timely fashion, resulting in per diem calculations that are not current for rate setting purposes. When cost reports are finally settled, our programs have operated on actual revenues of 80 percent of the per diem. In addition, many of our patients qualify for the Medicaid co-pay. If the Medicaid co-pay is lost due to proposed Medicaid cuts or changes in policy, our community-based Partial Hospital programs would cease to operate.

Partial Hospital programs are a proven, cost-effective model of care for a population of clients with severe mental illness. The service is a vital component of the continuum of mental health care in Massachusetts. We strongly object to any reduction in the rate in 2006 and respectfully request that CMS-1501-P: Proposed Changes to Hospital Outpatient PPS 2006 Rates not be implemented as proposed.

If you should have any questions, please contact me at 508-647-8385.

Thank you for your consideration of our recommendation.

Sincerely,

Betty Funk

Elizabeth Funk
President and Chief Executive Officer

Cc: Constance Peters, Vice President, MHSACM

Submitter : Mr. Santiago Munoz **Date:** 09/16/2005

Organization : University of California Office of the President

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1501-P-596-Attach-1.PDF

#596

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September 14, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Ave, SW
Washington, DC 20201

SUBJECT: **CMS-1501-P** – Proposed Medicare Hospital Outpatient Prospective Payment System Rates for Calendar Year 2006

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Medicare Outpatient Prospective Payment System (OPPS) proposed rule for Calendar Year (CY) 2006 issued by the Centers for Medicare & Medicaid Services (CMS) in July 2005. These comments are provided on behalf of the University of California (UC), Office of the President, Clinical Services Development Division, and UC's five academic medical centers (AMCs) located in Davis, Los Angeles, Irvine, San Diego, and San Francisco.

Together, the UC AMCs are the fifth largest healthcare delivery system in California, the leading provider of certain specialty services and medical procedures, and one of the state's largest providers of care to Medicare patients. Annually, the AMCs provide patient care services valued at over $3.3 billion. In alignment with its patient care work, the AMCs also play a critical role in a number of broad public-policy goals, including the education of health professionals and the advancement of medical science through cutting-edge research. Specifically, UC medical centers offer services that are essential to the health and well being of Medicare beneficiaries including a broad-array of highly specialized services, such as cancer centers, geriatric and orthopedic centers of excellence, organ transplant programs, and world class primary and preventive care.

The University is extremely concerned with the decline of its Medicare payments given our role in providing medical education and in serving extremely high-cost Medicare beneficiaries. In fiscal year 2004, the UC Medical Centers incurred aggregate Medicare OPPS losses in excess of $40 million. These losses threaten the viability of our clinical enterprise and our role as teaching hospitals. UC continues to urge Congress to provide adequate Medicare payments to its hospitals and urges CMS to ensure the Congressional intent of hospital payment updates is fully implemented on a programmatic level. Further, while UC's comments address the most significant areas of concern for its AMCs, it urges CMS to make changes to the proposed rule that would prevent further decline in Medicare payments to its medical centers.

- OPPS Payment Updates

The proposed rule follows the current law requirement that the base payment rate be increased to reflect the full hospital inpatient market basket of 3.7 percent for FY 2006. However, the CMS data indicates that the actual average outpatient payments will increase only by an estimated 1.9 percent because of the expiration of several Medicare Modernization Act (MMA) provisions. This reduction will be exacerbated for teaching hospitals by the changes to the wage index calculation. **The UC respectfully requests that CMS provide detailed information on how it derived its impact estimates.**

- Outlier Payments

Outlier payments are a critical component of the PPS. For the UC hospitals, the outliers help mitigate the financial losses of high-cost cases. For 2006, CMS proposes to set the target for aggregate outlier payments at 1.0 percent of aggregate total payments under OPPS. Further, to ensure that estimated 2006 outlier payments would equal one percent of total outpatient PPS payments, CMS proposes to increase the fixed-dollar threshold to $1,575, while maintaining the multiplier threshold at 1.75. UC is concerned that the threshold may be too high and may result in aggregate outlier payment amounts that are less than the budget neutrality target. Further, the proposed rule contains no analysis on the redistributive impact of these proposed changes. **The UC respectfully requests that CMS publish data to evaluate the proposed rule before any changes are implemented.**

- Adjustments for Certain Hospital Categories

Under current law CMS is allowed to adjust the payment system in a budget neutral manner if it determines such adjustments are necessary to ensure equitable payment distribution. Unfortunately, the proposed rule includes no discussion of the special role and costs related to medical education. **The UC respectfully requests that CMS conduct an analysis to determine the appropriateness of including a teaching adjustment.**

- APC Relative Weights, Grouping, and Payment Rates

Current law requires the review and revision of the relative payment weights for Ambulatory Payment Classifications (APC) at least annually. The proposed rule includes a number of coding, APC assignment, and "pseudo single claim" changes. The UC is concerned that these changes may adversely impact payments for high volume and costly outpatient services.

The UC AMCs have worked aggressively to ensure patients are placed in the most appropriate clinical setting and adopted new costly technologies designed to improve patient care. Many of these efforts emphasize outpatient services to Medicare beneficiaries, help improve access, and address capacity issues. It is critically important that the OPPS not penalize hospitals, such as the UC, for efficient treatment and for ensuring that patients receive the right care at the right time in the right place.

The UC respectfully requests that CMS provide additional information on the impact of each of the proposed policy change and information on the combined impact of all changes. We also request that CMS provide a public use file that demonstrates the impact of each proposed change to enable providers to review these impacts, assess the impact on their operations, and provide a basis for providing thoughtful comments to CMS.

- Payments for Drugs and Biologicals

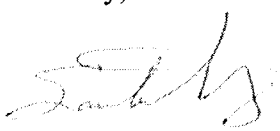
The proposed rule would continue to pay hospitals separately for drugs and biologicals whose per day costs exceed $50 or bundling the payment with the appropriate procedure code when the drugs cost less than $50. The MMA provided that for CY 2006, payment payable for drugs and biologicals be equal to the average acquisition costs adjusted for overhead costs. Conversely, the current payment method is based on average wholesale price. CMS has determined that the average acquisition costs for drugs and biologicals is equivalent to the average sales price (ASP).

The payment under the proposed rule would be ASP plus 6 percent for acquisition costs and 2 percent to cover hospital handling costs. This would result in overall drug payments, including the drug itself and the associated handling payment, of ASP plus 8 percent, which is a rate that CMS indicates is equivalent, on average, to the mean cost for drugs derived from hospitals claims data. The UC agrees that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare.

We recommend that the 2 percent adjustment for drug handling be treated as a temporary measure until CMS develops an approach to establish differential add-on payments for drug handling costs to account for a wide variety of drug handling categories.

Thank you for the opportunity to comment on the Medicare Outpatient PPS proposed rule for CY 2006. If there are questions or if I can provide any additional information or input, please contact me at 510-987-9062 or santiago.munoz@ucop.edu.

Sincerely,



Santiago Muñoz, Executive Director
Clinical Services Development

Submitter : **Ms. Melissa Dehoff** **Date: 09/16/2005**

Organization : **The Hospital & Healthsystem Assoc. of Pa**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1501-P-597-Attach-1.DOC

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

September 16, 2005

Attachment #597

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Ref: [CMS-1427-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2006 Payment Rates (70 *Federal Register* 42673), July 25, 2005.

Dear Dr. McClellan:

On behalf of The Hospital & Healthsystem Association of Pennsylvania (HAP), which represents approximately 250 member institutions, including 125 stand-alone hospitals and another 120 hospitals that comprise 32 health systems across the state, we appreciate this opportunity to comment on the proposed rule, Changes to the Outpatient Prospective Payment System and FY 2006 Rates, published in the May 4, 2005, *Federal Register.* Our comments focus on the major provisions of this proposed rule, which include: changes to payments for handling costs hospitals incur for separately paid drugs, increases in the threshold for the outlier policy, reduced payments for multiple imaging procedures, and changes to payments for rural hospitals.

Ambulatory Payment Classification (APC) Relative Weights

HAP continues to support the current law that requires CMS to review and revise the APC relative weights at least annually, as well as their use in hospital data to set these payment rates. The use of true hospital data more accurately reflects the costs that hospitals incur to provide outpatient services. **HAP supports the use of the most recent claims and cost report data used to set the 2006 payment weights and rates.**

In the proposed rule, CMS continues to include more claims data in the calculation of the APC payment rates, especially with multiple procedure claims that contain charges for more than one service or procedure. CMS proposes to expand the number of HCPCS codes (from 383 in 2005 to 404 in 2006) that are bypassed on a claim. In addition, CMS is proposing to continue using the date of service matching as a tool for creation of pseudo single claims. HAP supports the use of multiple procedure claims, as this data improves hospital cost estimates. In addition, HAP supports the expanded list of codes for bypass, as it appears unlikely theses codes would have charges that would be packaged into other services or procedures.

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While the proposed rule provides a detailed description of the methodology used to calculate the APC weights, it does not provide adequate information for hospitals to evaluate the impact of each of the proposed changes independently or in combination. **HAP would like CMS to provide a public use file that shows the impact of each individual proposed change in methodology in order for hospitals and other health care providers to review the file to determine how the changes would affect their operations and provide a basis for submitting comments to CMS.**

With regard to the bypass list, HAP requests clarification from CMS as to why only some of the office visit and consultation service evaluation and management codes are included in the bypass list. This list contains some office visit and consultation services codes, but not all of them. For example, the list includes HCPCS codes 99213 and 99214, but not 99212 and 99215.

Proposed Changes to Packaged Services

In the proposed rule, CMS mentioned the establishment of a Packaging Subcommittee to the APC Panel to review all the procedural CPT codes with a status indicator of "N." HAP commends CMS and this subcommittee for initiating this process and encourages CMS to continue to work with this subcommittee in order to conduct further review of "N" status codes for the purpose of identifying those that should be separately payable. Currently, when hospitals provide services described by the "N" status codes alone, there is no way to be reimbursed for the costs of providing these services.

Partial Hospitalization

CMS proposes to apply a 15 percent reduction in the per diem payment rate for partial hospitalization services in 2006. HAP is concerned this reduction could have serious negative consequences for the financial viability of partial hospitalization services and could endanger Medicare beneficiary access to these critical services. These services have already been very vulnerable, with many programs closing or limiting the number of patients that can be accepted.

While the proposed rule reflects CMS's concern over the volatility of the community mental health center (CMHC) data and the instability of charges that are submitted, HAP supports their intent to monitor their costs and charges for these services, as well as working with the CMHCs to improve their cost reporting so payments can be calculated based on better objective data.

Although HAP recognizes that CMS's proposal was made in order to avoid a more significant reduction in the payment rate for these services, we do not believe that hospitals that offer partial hospitalization services should be penalized for the instability in data reporting that originates from CMHC-based services. **HAP would like to request that CMS maintain the payment rates for partial hospitalization services at the 2005 levels. This would allow payment stability for these services and protect beneficiary**

access while allowing CMS sufficient time to address the instability in the CMHC data.

Conversion Factor

HAP gathers that CMS will follow the practice used in previous years of utilizing the same market basket update published in the final inpatient PPS rule for the purposes of the outpatient PPS. As part of this, it is noted that in the final inpatient PPS rule, CMS changed the market basket estimation methodology to provide a better estimate of hospitals cost increases. We assume that this change will also be carried forward into the final outpatient rule.

Expiring Hold Harmless Provision for Transitional Corridor Payments for Certain Rural Hospitals

HAP is concerned about the impact the December 31, 2005 expiration of the transitional corridor hold harmless payments will have on small rural hospitals. While these payments will continue to be available to cancer and children's hospitals, small rural hospitals are very vulnerable facilities that provide important access to care for populations in their communities.

Rural Hospital Adjustment

In the proposed rule, CMS discussed the study that was completed to determine if rural hospital outpatient costs exceed urban hospital outpatient costs. CMS indicated that they conducted an explanatory regression analysis that included three specific classes of rural hospitals: rural sole community hospitals (SCHs), rural hospitals with less than 100 beds that are not rural sole community hospitals and other rural hospitals. This analysis was conducted to determine whether the difference in costs that was found between rural versus urban hospitals was uniform across rural hospitals or whether all of the variation was attributable to a specific class of rural hospitals. The results of the regression analysis led CMS to its conclusion that rural SCHs are more costly than urban hospitals. As a result, CMS proposes to provide a 6.6 percent payment increase for rural SCHs for 2006.

Table 6 in the proposed rule provides the regression results for unit outpatient cost for rural SCHs. HAP is concerned that this data does not separately set out the regression results for rural hospitals with 100 or fewer beds that are not rural SCHs. While CMS implies that the results for this category of hospitals were not significant, we feel it is important to report these results for these hospitals, as they will be the facilities that will be losing their hold-harmless protection in 2006. **HAP requests that CMS either present the regression results for rural hospitals with 100 or fewer beds that are not SCHs in Table 6 or provide an explanation why these results cannot be reported.**

Outlier Payments

CMS proposes to reduce the outlier pool to 1 percent of total outpatient PPS payments and states that the fixed-dollar threshold should be increased by $400 to $1,575 in order to ensure that estimated 2006 outlier payments would equal 1 percent of total outpatient

PPS payments. Therefore, in order to qualify for an outlier payment, the cost of a service would have to be both more than 1.75 times the APC payment rate and at least $1,575 more than the APC rate.

HAP supports the need for an outlier policy within all payment systems, including outpatient PPS; however, we have great concern that CMS has set the thresholds for outliers in this proposed rule too high. HAP requests additional clarification from CMS regarding how a $400 increase in the fixed-dollar threshold was appropriate and how the $1,575 fixed-dollar threshold was calculated.

In 2006, CMS is proposing to set aside 1 percent for outliers, rather than 2 percent that has been used for the past four years. However, CMS does not publicly release data regarding how much of the outlier set-aside was actually spent in prior years. Due to the significant changes to outlier policies proposed for 2006, HAP is concerned that Medicare may not actually spend the outlier target set-aside.

HAP urges CMS to publish data in the final rule on: actual outlier payments made in 2004 and prior years, actual outlier payments for 2005 be reported as soon as CMS is able to obtain complete data and continue to report this data in the future. CMS is able to obtain this information for inpatient services; therefore, CMS should be able to obtain the data and report it for outpatient services. Costly databases should not have to be purchased by those interested in obtaining this data to determine whether these thresholds are being set at the correct level. HAP is concerned that CMS cannot set the outlier threshold at an appropriate level if it does not know what is actually being spent on outliers.

New Technology APCs

The increase of G codes and C codes with overlapping descriptions with CPT codes has become confusing and very demanding for coders in hospitals. This has led to incorrect coding and unreliable data available for rate setting. The requirement that an application for a new CPT code be submitted at the time of a New Technology APC application will minimize the need for expedited issuance of temporary G or C codes. The HCPCS level II G and C codes are generally not accepted by payers other than Medicare, which requires hospitals to have two different codes to report the same procedure, depending on the payer. This new process will reduce the duplication of codes so that it will start the process right as CPT rather than starting with a New Technology assignment without a way to report the procedure. Having a CPT code available for new technology will simplify the billing and coding process for hospitals as they will be using one set of codes for all payers as much as possible.

Hyperbaric Oxygen

HAP supports CMS's decision to no longer use the respiratory therapy cost-to-charge ratio (CCR) for purposes of calculating the median cost for hyperbaric oxygen therapy (HBOT) and instead use the hospital's overall cost-to-charge ratio. However, as some

hospitals currently report their costs for HBOT in a separate HBOT line on their cost report, HAP recommends that for 2006, CMS calculate the median rate for HBOT using the HBOT CCR for those hospitals that have such separate reporting, and use the overall hospital CCR otherwise. In order to develop more accurate rates for HBOT in the future, CMS should encourage hospitals to report their HBOT costs on a separate HBOT line on their cost report. This should not be administratively difficult for hospitals because HBOT revenues are already captured in a specific separate revenue code, so this would involve only a change in where costs for HBOT are reported on the cost report.

NonPass-Throughs

In the proposed rule, CMS evaluates three alternatives for setting 2006 payment rates for specified covered outpatient drugs: (1) average and median purchase price data for drugs purchased from July 1, 2003 to June 30, 2004 derived from a General Accountability Office survey of 1,157 hospitals; (2) the average sales price (ASP) data from the fourth quarter of 2004; and (3) mean and median costs derived from the 2004 hospital claims data. After reviewing each option, CMS proposes to pay ASP+6 percent for separately payable drugs and biologicals in 2006.

HAP supports this proposal, as it is the best estimate of average acquisition cost available at this time. This also provides an additional benefit of providing consistent payment rates across the hospital outpatient PPS and the physician fee schedule payment systems. HAP also supports the APC Panel's recommendation that CMS track the drug codes to be paid at ASP+6 percent, with a particular focus on those drugs whose rates would fall significantly in 2006.

Pharmacy Overhead and Drug Handling Payment Rate Adjustment

In this proposed rule, CMS considers Medicare Payment Advisory Commission (MedPAC) recommendations on adjusting the APC rates for separately payable drugs to take into account pharmacy overhead and drug handling costs. To accommodate this, CMS proposes to establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals and to instruct hospitals to charge the appropriate pharmacy overhead C-code for overhead costs associated with each administration of each separately payable drug and biological based on the code description that best reflects the service the hospital provides to prepare the product for administration to a patient. CMS does not have separate hospital charge data on pharmacy overhead and proposes to pay for these costs based on 2 percent of the ASP. This would result in overall drug payments of ASP+8 percent, which is a rate that CMS states is equivalent to the mean cost for drugs derived from hospital claims data.

HAP agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient departments are significant and should be reimbursed by Medicare. However, the ASP+2 percent adjustment for drug handling is not adequate for certain drugs that have very high handling costs due to special equipment or procedures related to the drug's toxicity or preparation

requirements. HAP recommends that CMS consider freezing payments for those drugs whose payments would decline significantly from the 2005 rates. CMS should work with hospital and pharmacy stakeholders in the future to develop an approach to establish differential add-on payments for drug handling costs to account for a variety of drug handling categories.

HAP strongly disagrees with CMS's proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs and biologicals and to utilize the three proposed C-codes for charging these overhead costs. Not only would this require extensive time from the hospitals, it would also negatively impact their operations.

There are many administratively burdensome and complex issues that CMS needs to consider regarding this proposal of charging for drug handling through the use of new C-codes. Most importantly is that Medicare providers are required to maintain uniform charges for all payers. Thus, it is impossible to charge Medicare for a drug at a rate that does not reflect handling costs and charge other payers for the same drug at a higher rate that does not reflect handling costs. Other concerns regarding this issue include:

- One charge master is utilized in many hospitals for both inpatient and outpatient services. CMS needs to provide clarification on how providers will be expected to report drug charges in the inpatient setting versus the outpatient setting if the handling charge must be separated out of the drug charge for the outpatient setting.
- The normal mark-up formula for all pharmacy items, as well as the handling costs for some of these drugs and biologicals will need to be evaluated. Essentially, hospitals would need to identify the handling charges for separately payable drugs under Medicare and pull them out, while the drug handling charges for packaged drugs would remain incorporated within the overall charge for the drug. This process would be both very complex and time-consuming.
- For each separately payable drug, hospitals will need to assign the handling charge to one of CMS's proposed new drug handling C-codes. Due to the fact that C-codes are only recognized and accepted by Medicare, not other payers, hospitals will need to modify their billing systems to separate out the drug handling from the drug charge for Medicare claims but bill them as a single line item for other payers.
- Clarification needs to be provided by CMS regarding how the drug handling C-codes would apply when a hospital pharmacy mixes multiple doses of a drug for a patient. Hospitals need to know whether a single C-code for handling costs in this case be reported or multiple C-codes.
- Drug pricing is generated via a pharmacy charging system that is often located outside the hospital's normal charging system. This system may not be able to accommodate the proposed C-codes.

The APC Panel has proposed that CMS expand the application of its proposed drug handling coding and payment methodology to drugs that are packaged into other APCs. **HAP opposes this proposed expansion, as this would greatly increase the coding and administrative burden on hospitals due to the number of drugs that would require special charging practices for Medicare purposes.** Generally hospitals do not provide detailed billing for drugs that are not separately paid. Therefore, it would be extremely difficult for hospitals to bill the right drug handling C-code for packaged drugs. Additionally, many hospitals that utilize a paperless billing system also use an imaging system to generate bills for patients. Due to the large volume of drugs used in hospital outpatient departments, expanding the drug handling coding requirements to all these drugs, regardless of packaging status, would greatly increase hospital administrative costs associated with this proposal. **HAP recommends that CMS collect further data on drug handling of C-codes and develop alternatives, as well as simpler solutions for ensuring that hospitals are appropriately paid for their pharmacy overhead and drug handling costs.** Rather than requiring separate coding systems, an approach should be developed that incorporates the payments for drug handling directly into the payment rate for the drug itself.

Should this policy be incorporated into the final rule, HAP would request that CMS provide for a grace period of at least six months after implementation of the 2006 outpatient PPS to allow hospitals to make system changes and educate pharmacy staff, hospital finance staff, and coders on the required use of the drug handling "C" codes.

Drug Administration

For OPPS billing purposes, CMS proposes to continue their policy of using CPT codes to bill for drug administration services provided in the hospital outpatient department. **HAP supports CMS's proposed continuation of this policy.** Using CPT codes simplifies the administrative burden for the coding of drug administration since hospitals can use the same codes for both Medicare and non-Medicare payers.

Due to the significant changes expected with the new 2006 CPT codes for drug administration, instruction, and clarification on the application of these new codes will need to be provided to hospitals. Some of the issues requiring clarification include:

- Definitions of what constitutes an initial vs. subsequent infusion vs. concurrent infusion.
- Definition of hydration and how it is different from a hydration that is given for therapeutic reasons.
- How are infusions or titrations to be reported? Many times they are established with a documented start time and are administered via pump. As a result, many infusions are maintained by equipment function rather than manual intervention. In these cases, a nurse may be aware of the start time of an infusion and may document it; however, it is unlikely that the stop time will be documented.

- How the code application may be similar or different for the hospital outpatient department as compared to the physician setting. This is especially true with non-oncology providers of infusion and injection services since they often cross departments.

E/M Services

Since outpatient PPS was implemented, clinic and emergency department visits have been coded using the same CPT code as physicians. CMS has recognized that the existing E/M codes correspond to different levels of physician effort but do not adequately describe non-physician resources. Back in 2003, hospitals anticipated that CMS would propose a national, uniform E/M coding system; however, they chose not to do so. This system was not developed and implemented in 2004 and 2005, and is not considered as a part of this proposed rule. **HAP is disappointed that the 2006 proposed rule does not propose national guidelines for facility E/M reporting.** While CMS continues to develop and test the new codes, hospitals are still without a standard methodology for reporting E/M services. This not only puts hospitals at compliance risk for multiple interpretations of the level of service that should be coded and billed, but also affects CMS's ability to gather consistent data on services provided in the emergency department and hospital clinics.

Blood and Blood Products

CMS proposed to continue to make separate payments for blood and blood products through individual APCs for each product. CMS also proposes to establish payment rates for blood and blood products based on 2004 claims data, utilizing an actual or simulated hospital blood-specific cost-to-charge ratio to convert charges to costs for blood and blood products. For blood and blood products whose 2006 simulated medians would experience a decrease of more than 10 percent in comparison to their 2005 payment medians, CMS is proposing to limit the decrease in medians to 10 percent.

While this approach will result in payment increases for many blood and blood product APCs, the payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood product APCs will continue to decline under this methodology. The proposed rate for many of these blood products is significantly below hospitals' actual acquisition cost for blood. **HAP recommends that CMS set 2006 rates at the greater of: (1) the simulated medians calculated using the 2004 claims data; or (2) the 2005 APC payment medians for these products.**

Observation Services

Medicare currently provides a separate observation care payment for those patients with congestive heart failure (CHF), chest pain, and asthma. To reduce the administrative burden on hospitals when attempting to differentiate between packaged and separately payable observation services, CMS is proposing to discontinue current HCPCS codes for observation services (G0244, G0263, and G0264) and create two new HCPCS codes to

be used by hospitals to report all observation services. These new codes are GXXXX (Hospital observation services, per hour) and GYYYY (Direct admission of patient for hospital observation care). CMS also is proposing to shift determination of whether or not observation services are separately payable under APC 0339 from the hospital billing department to the outpatient PPS claims processing logic contained in the Outpatient Code Editor (OCE) system.

HAP supports the concept of allowing the OCE logic to determine whether services are separately payable. This will result in a simpler process for ensuring payment for the provision of covered outpatient observation services. However, we feel the OCE logic could be used even more efficiently to make the HCPCS code GYYYY unnecessary. If the hospital bills the GXXXX code and the claim does not include a 45X (emergency dept.) or 516 (urgent care center) revenue code, the OCE logic should determine that this was a direct admission to observation care. If the hospital bills the GXXXX code with a 45X OR 516 revenue code, it should be clear that the patient came in through the emergency department or urgent care center. Once this logic is programmed into the OCE, the system would determine whether the observation is a result of a direct admission or not and pay accordingly.

Inpatient Procedures

CMS proposes to remove 25 procedures from the inpatient only list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and assign them to clinically appropriate APCs. **HAP would like to request that CMS eliminate the inpatient only list entirely.** The physicians, not the hospitals per se, determine where procedures can be safely performed, as well as whether a patient's condition warrants an inpatient admission. Under current rules, if a physician determines that a service can be safely performed in an outpatient setting, the hospital is penalized if that procedure is on the inpatient only list. Should this list not be eliminated, an appeals process should be developed to address those circumstances in which payment for a serviced provided on an outpatient basis is denied because it is on the inpatient only list. This would give the provider an opportunity to submit documentation to appeal the denial.

Ancillary Outpatient Services

CMS expresses concern in the proposed rule over the increase in the volume of hospital claims that were billed with the –CA modifier during the 2003-2004 time frame. The volume went from 18 to 300 claims during this one-year period. This modifier was initially used to address situations where a procedure on the inpatient only list must be performed to resuscitate or stabilize a patient in a hospital outpatient department with an emergency, life-threatening condition and the patient dies before being admitted as an inpatient. HAP agrees that this modifier should only be used in unusual and rare circumstances and is unsure for the reason behind the volume increase in these claims. Improper usage of the modifier could be one cause. It could also be a result of this being a relatively new modifier and hospitals were only beginning to become aware of it.

Another possibility may be Medicare beneficiaries that arrive for a scheduled procedure and due to complications developing, the physician found it necessary to provide a service they had not otherwise intended to perform in an outpatient setting.

HAP would like to see the –CA modifier policy maintained and preserved as it supports an important function for hospitals. HAP supports CMS' continuing to closely monitor hospital use of this modifier. CMS may benefit from providing additional education on the appropriate use of this modifier.

Multiple Diagnostic Imaging Procedures

Under the current OPPS, hospitals billing for diagnostic imaging procedures receive full APC payments for each service on a claim, regardless of how many procedures are performed using a single imaging modality and whether or not contiguous areas of the body are studied in the same session. In this proposed rule, CMS proposes reducing payment when multiple imaging services are provided on the same day. In conjunction with a recommendation from the Medicare Payment Advisory Commission (MedPAC), CMS proposes to make full payment for the highest paid imaging service and pay 50 percent of the APC payment rate for every additional procedure within the same "family" of procedures performed in the same session. The proposed rule outlines 11 "families" of imaging procedures by imaging modality and by contiguous body area.

HAP opposes the implementation of this policy without better justification and more substantial, hospital-based data to support the policy for the following reasons:

- CMS did not examine hospital cost data when developing this policy—the level of the discount was determined by relying on Medicare physician fee schedule practice expense data. There is no evidence to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies, should they exist.
- Different methods are used by CMS to set payments in physician offices and hospital outpatient departments. Physician fee schedule amounts are based on expert opinion of the resources required to perform different services while the outpatient rates are set based on hospital cost data. CMS should conduct analyses using hospital data before implementing this policy.
- The proposed rule provides little specifics with regard to how this policy will be implemented and has a lack of detail provided.
- The proposed rule indicates the policy will be budget neutral, however, no detail is provided on how the impact of the multiple imaging procedures discount was estimated or how the budget neutrality factor was adjusted to account for this.

HAP agrees with the APC advisory panel recommendation that this policy should not be implemented without additional analysis and better proof.

Interrupted Procedures

CMS is proposing to decrease payment from 100 percent to 50 percent for interrupted procedures coded with modifiers 52 (discontinued procedure, no anesthesia provided) or 74 (procedure discontinued after administration of anesthesia). However, the proposed rule does not indicate that an analysis was conducted to support this reduction in payment. A detailed claims analysis is needed and evidence supporting this reduction should be established before proceeding and implementing.

Physician Oversight of Nonphysician Practitioners

HAP supports CMS's proposal to defer to state law regarding the need for physicians to review and sign the medical records for outpatients cared for by nonphysician practitioners in critical access hospitals (CAHs). However, we also recommend that CMS extend the application of this policy to apply to physician review of inpatient records for patients cared for by nonphysician practitioners. If state law permits these practitioners to practice independently, CMS should not require physician oversight in either the outpatient or inpatient setting. We agree that State laws providing independent practice authority generate sufficient control and oversight of these nonphysician practitioners and we do not believe that quality of care is reduced by non physician practitioners.

Sincerely,

Paula A. Bussard

PAULA A. BUSSARD
Senior Vice President, Policy & Regulatory Services

Submitter : Mr. Jim Potter **Date:** 09/16/2005

Organization : American Speech-Language-Hearing Association

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-598-Attach-1.DOC

Attachment #598

AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

September 16, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1501-P
Mail Stop C4-26-05
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Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 payment rates (*Federal Register*, July 25, 2005, pp. 42674-43011)

Dear Dr. McClellan:

The American Speech-Language-Hearing Association (ASHA) is the professional and scientific association of more than 120,000 speech-language-pathologists, audiologists, and speech, language, and hearing scientists. We appreciate the opportunity to comment on the proposed rule for next year's hospital outpatient prospective payment system (OPPS).

Device-Dependent APCs

APC 259 – Level VI ENT Procedures (cochlear implantation). Ambulatory Payment Classification (APC) 259 represents a single surgical procedure (CPT 69930) and the associated device. The proposed payment amount ($21,643) does not cover the cost of the procedure and would continue Medicare's unintended role of discouraging cochlear implantation in the outpatient setting. Although infrequently required as an inpatient procedure, the Medicare payment for inpatient cochlear implantation also creates a large disincentive for facilities to provide this service. ASHA requests that CMS perform more thorough hospital cost analyses in order to allow this life-changing surgical implant to be available to beneficiaries who are, for all practical purposes, totally deaf. For an elderly person, a cochlear implant can mean the difference between independence and

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dependence. The cost-effectiveness of cochlear implantation has been well-documented by a large body of evidence-based literature. A comprehensive review of cochlear implantation is found in "Cochlear Implants in Adults and Children" (National Institutes of Health, Consensus Development Conference Statement, May 15-17, 1995). The complete conference statement is found at:
consensus.nih.gov/cons/100/100_statement.htm

Most likely, CMS will not have time to complete a new hospital cost analysis of cochlear implants before the final rate schedule must be published. We therefore ask that CMS rely on an expert organization's analysis (The Lewin Group) of the 2004 hospital claims for this procedure. The complete Lewin Report, cited below, is attached to the OPPS comment letters submitted by Boston Scientific (Advanced Bionics), Cochlear Corporation, and MED-EL Corporation.

With the exception of the proposed 2005 rates, ASHA has argued every year since the inception of OPPS, that the payment for cochlear implantation falls below or at the cost of the device itself. Even if the cost of the device is covered, the hospital incurs a significant loss if there are no funds left over to cover the cost of the surgical suite, staff and surgeon. The proposed rate of $21,643 is 15% below the 2005 rate of $25,307. We once again implore CMS to adjust its rates to cover actual costs.

The inaccurate representation of the device costs in 2004, the basis for the proposed APC rate, is analyzed in a report prepared by The Lewin Group, Inc., dated September 1, 2005, "Evaluation of the Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for Cochlear Implantation Devices." Lewin analyzed the CMS cochlear claims and invoices. The weighted *average* invoice price for the device was $21,827. This is in great contrast to the *median* device cost, $16,408, the methodology used by CMS in its calculation of the APC rate. The proposed rate reflects an average device cost shortfall of $5,419 for each cochlear implant performed. The payment rate calculated by Lewin for APC 259, incorporating the revised cost of the device, is $27,192.

ASHA endorses the adoption of $27,192 as the payment rate for this APC. This will allow a hospital to cover costs of the cochlear device and contribute to the cost of the operating room, staff, and surgeon.

The lower proposed rate will jeopardize access for implants and follow-up care because there currently are only about 350 cochlear implant centers nationwide. When one center discontinues its cochlear program, area beneficiaries are forced to travel a considerable distance for access to another center. In 2005, Sarasota Memorial Hospital was forced to close its cochlear program in which 42% of its implant patients were Medicare beneficiaries. Lower 2006 Medicare payment rates will increase the possibility of

additional centers closing. It appears that some hospitals have established a quota for Medicare cochlear implants. An audiologist reported to ASHA that a Florida hospital generally allows Medicare implants just for public relations purposes and that number is very limited.

ASHA appreciates the opportunity to comment on the CMS proposal. For further information, please contact Mark Kander, ASHA's director of regulatory analysis, at 301-897-0139 or at mkander@asha.org.

Sincerely,

// s //

James G. Potter
Director, Government Relations & Public Policy

Submitter : Mr. James Adams

Date: 09/16/2005

Organization : Coast Plaza Doctors Hospital

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

Hello,
Thank you for the opportunity to comment on CMS-1501-P
(see attachment).
James Adams

CMS-1501-P-599-Attach-1.DOC

Attachment #599

September 16, 2005

Centers of Medicare and Medicaid Services
Department of Health and Human Services

Attention: CMS-1501-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Regarding: Partial Hospitalization Response on Proposed Changes
To the Hospital Outpatient PPS-CMS-1501

Coast Plaza Doctors Hospital is an acute care Hospital in Southern California. In addition to our medical services we have a psychiatric department that provides outpatient and partial psychiatric hospitalization. These services are greatly needed for the mentally ill in our community. Our Partial Hospitalization Program serves approximately 10,400 patients on an annual basis.

We are requesting that the proposed 14% rate reduction for partial hospitalization services in CY 2006 be stopped and re-considered. We strongly support the position of the Association of Ambulatory Behavioral Healthcare in the proposed changes in reimbursement in this area.

Please consider not cutting the PHP reimbursement so drastically when most medical costs are actually increasing by 3.5% annually. These psychiatric services need to be supported by reasonable reimbursement rates that sufficiently cover the costs of providing quality services to such needy populations.

Thank you for your consideration.

Sincerely,

Craig Garner, CEO
Coast Plaza Doctors Hospital, and

James F. Adams, RN, MSN,CNS
Program Director, PHP